

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020924

CHEMISTRY REVIEW(S)

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-924

DATE REVIEWED: 3-25-99

REVIEW #: 2

REVIEWER: David Lewis

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	03-20-98	03-24-98	04-08-98
Amendment	03-16-99		

NAME & ADDRESS OF APPLICANT:

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois
60073-0490

DRUG PRODUCT NAME

Proprietary:

Cernevit™-12 IV Multivitamins

Established:

Code Name/#:

Chem.Type/Ther.Class:

1S

PHARMACOL. CATEGORY/INDICATION: Multivitamins for Intravenous Infusion/ Indicated as a daily multivitamin maintenance dosage for adults and children age 11 and above receiving parenteral nutrition.

DOSAGE FORM:

Injection

STRENGTHS:

N/A

ROUTE OF ADMINISTRATION:

Intravenous

Rx/OTC:

☒ Rx ☐ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

See Chem. Review # 1, p. 1.

SUPPORTING DOCUMENTS: See Chem. Review # 1

RELATED DOCUMENTS (if applicable): See Chem. Review # 1

CONSULTS: Microbiology Consult - see Micro. Review # 1 (Acceptable)

REMARKS:

The applicant committed to provide replies to each of the deficiency/information requests within 12 months of approval of NDA 20-924. Revisions made to the draft package insert and labels for the drug product have been received and are found acceptable. According to an agreement reached in a meeting between the Agency and [REDACTED] The site inspection report is now acceptable, according to the OC.

CONCLUSIONS & RECOMMENDATIONS: The application is approvable, regarding chemistry,
manufacturing and controls information. [REDACTED]

cc:

Org. NDA 20-924

HFD-510

HFD-820/Chemist/D Lewis/DGWu

HFD-510/S. McCort/CSO

HFD-102/

R/D Init by: /S/ [REDACTED]

3/5/99

Filename: NDA 20-924, Review

/S/ [REDACTED]

David B. Lewis, Ph.D.
Review Chemist

APPEARS THIS WAY ON ORIGINAL

N/C 0025
MAR - 2 1999

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-924

DATE REVIEWED: 2-11-99

REVIEW #: 1

REVIEWER: David Lewis

SUBMISSION TYPE

ORIGINAL

DOCUMENT DATE

03-20-98

CDER DATE

03-24-98

ASSIGNED DATE

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Rx/OTC:

X Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

1. Ascorbic Acid (Vitamin C)
2. D-Biotin
3. Cholecalciferol (Vitamin D₃)
4. Cocarboxylase (Vitamin B₁)
5. Cyanocobalamin (Vitamin B₁₂)
6. Dexpantenol (Vitamin B₅)
7. Folic Acid
8. Nicotinamide (Vitamin B₃)
9. Pyridoxine•HCl (Vitamin B₆)
10. Retinol palmitate (Vitamin A)
11. Riboflavin Sodium Phosphate (Vit. B₂)
12. DL-a-Tocopherol (Vitamin E)
13. Glycine
14. Glycocholic Acid
15. Soybean lecithin
16. Sodium hydroxide, or
17. Hydrochloric Acid